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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte WILLIAM J. CURATOLO, SCOTT M. HERBIG, and
JAMES A.S. NIGHTINGALE

Appeal 2010-009640
Application 09/770,562
Technology Center 1600

Before DONALD E. ADAMS, FRANCISCO C. PRATS, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 1, 4, 23, 36, 37, 49-51, and 53-56 (App. Br. 2).¹ We have jurisdiction under 35 U.S.C. § 6(b).

¹ “Claims 2-3, 5-22, 24-27, 39-48 and 52 have been cancelled and claims 28-38 and 38 have been withdrawn” (App. Br. 2).

STATEMENT OF THE CASE

The claims are directed to a composition of matter comprising a spray dried solid dispersion. Claim 1 is representative and is reproduced below:

1. A composition of matter comprising a spray dried solid dispersion, which dispersion consists of a sparingly water-soluble drug and hydroxypropyl methylcellulose acetate succinate (HPMCAS), said drug being molecularly dispersed and amorphous in said dispersion and having a drug:polymer weight ratio between 1:0.4 and 1:20.

Claims 1, 4, 49-51, and 53-56 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Miyajima.²

Claims 1, 4, 49-51, and 53-56 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Kigoshi.³

Claims 1, 4, 49, and 53-56 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hikosaka.⁴

Claims 1, 23, 50, and 51 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Miyajima or Kigoshi.

Claims 1, 4, 36, 37, 49-51, and 53-56 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Kigoshi, Madhusoodanan,⁵ and Bymaster.⁶

We affirm.

² Miyajima et al., EP 0 344 603 A1, published Dec. 6, 1989.

³ Kigoshi, EP 0 784 974 A1, published Jul. 23, 1997.

⁴ Hikosaka et al., JP 57-176907, Oct. 30, 1982.

⁵ Madhusoodanan, et al., *Efficacy of risperidone treatment for psychoses associated with schizophrenia, schizoaffective disorder, bipolar disorder, or senile dementia in 11 geriatric patients: a case series*, 56 J. CLIN. PSYCHIATRY 514-518 (1995).

⁶ Bymaster et al., US 6,147,072, Nov. 14, 2000.

Anticipation:

Miyajima or Kigoshi:

Appellants have limited their response to the rejection over Miyajima and Kigoshi to representative claim 1 (*see* App. Br. 6 and 8). Accordingly, we will address the merits of these two rejections as they apply to claim 1.

ISSUE

Does the preponderance of evidence on this record support the Examiner's finding that Miyajima or Kigoshi teach the subject matter of Appellants' claim 1?

FACTUAL FINDINGS

FF 1. Miyajima teaches a composition "prepared by dissolving NZ-105 and HPMCAS in an organic solvent, removing the solvent by means of . . . spray-drying . . . to produce powder or particles of NZ-105 and HPMCAS" (Miyajima 4: 56-58; *see also* Ans. 3).

FF 2. Miyajima teaches that a "desirable result can be obtained by formulating an amount of 1-7 parts by weight . . . of HPMCAS per unit weight of NZ-105" (e.g., a drug:polymer weight ratio between 1:1 and 1:7) (Miyajima 5: 8-9; *see also* Ans. 4).

FF 3. Miyajima teaches that the drug NZ-105 has "poor solubility in water" (Miyajima 2: 34; *see also* Ans. 3-4).

FF 4. Kigoshi teaches that "xanthine derivatives or pharmacologically allowable salts thereof . . . are slightly soluble" in water (Kigoshi 2: 21-22; *see also* Ans. 4).

FF 5. Kigoshi's invention relates to "a solid dispersion comprising a xanthine derivative or a pharmacologically allowable salt thereof and a polymer" (Kigoshi 2: 26-27; *see also* Ans. 4).

FF 6. Kigoshi teaches the use of hydroxypropylmethyl cellulose acetate succinate (HPMCAS) as the polymer (Kigoshi 4: 8; *see also* Ans. 5).

FF 7. Kigoshi' dispersion has a drug to polymer ratio of 3:1 to 1:5 by weight (Kigoshi 4: 12-13; *see also* Ans. 5).

FF 8. Kigoshi teaches that the dispersion can be produced by spray drying (Kigoshi 4: 37-38 and 49-50; *see also* Ans. 5).

ANALYSIS

Miyajima:

Miyajima teaches a composition “prepared by dissolving NZ-105 and HPMCAS in an organic solvent, removing the solvent by means of . . . spray-drying . . . to produce powder or particles of NZ-105 and HPMCAS” (FF 1). Accordingly, we are not persuaded by Appellants’ contention that “Miyajima only teaches how to make three- and four- component compositions and none by spray-drying” (App. Br. 7). For the same reason we are not persuaded by Appellants’ contention that “Miyajima does not specifically teach how to make (i) any two-component dispersion of drug and HPMCAS alone or (ii) any dispersion by spray-drying” (*id.* (emphasis removed)). To the extent that Appellants contend that a prior art reference must exemplify the production of a particular composition of matter, we note that “anticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions *be enabled to one of skill in the art.*” *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 468 F.3d 1366, 1382 (Fed. Cir. 2006 (emphasis added)) (quoting *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1378 (Fed. Cir. 2001)). Appellants failed to establish that a person of ordinary skill in the art would not find Miyajima’s disclosure enabling.

Appellants failed to identify an evidentiary basis on this record to support a conclusion that Miyajima's drug is not amorphous. We are not persuaded by Appellants' intimation that since "Miyajima does not characterize the drug in the compositions as being amorphous or crystalline" it does not have that property (App. Br. 7). In the absence of evidence to the contrary, we find that the preponderance of evidence on this record supports a finding that the drug in Miyajima's composition is inherently both molecularly dispersed and amorphous in the dispersion, given that Miyajima uses the same dispersing polymer and spray drying technique used by Appellants.

Kigoshi:

We are not persuaded by Appellants' contention that Kigoshi fails to anticipate the claimed invention because it expressly teaches HPMCAS in addition to 21 other polymers that may be used to formulate the composition (App. Br. 8). *See, e.g., Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1376 (Fed. Cir. 2005) ("This court rejects the notion that one of these [fourteen skin benefit] ingredients [taught by the prior art] cannot anticipate because it appears without special emphasis in a longer list. To the contrary, the disclosure is prior art to the extent of its enabling disclosure"). Notwithstanding Appellants' contention to the contrary, we find the same to be true of Kigoshi's teaching of spray drying, as well as a number of other methods useful in producing the composition (*Cf.* App. Br. 8; FF 8).

We find no persuasive evidence or argument on this record to support Appellants' contention that "Kigoshi is non-enabling" (App. Br. 8). *See Impax Labs., Inc. v. Aventis Pharms. Inc.*, 468 F.3d at 1382.

CONCLUSION OF LAW

The preponderance of evidence on this record supports the Examiner's finding that each of Miyajima and Kigoshi teach the subject matter of Appellants' claim 1. Accordingly, we affirm the rejection of claim 1 under 35 U.S.C. § 102(b) as being anticipated by Miyajima. Because they are not separately argued claims 4, 49-51, and 53-56 fall together with claim 1. We also affirm the rejection of claim 1 under 35 U.S.C. § 102(a) as being anticipated by Kigoshi. Because they are not separately argued claims 4, 49-51, and 53-56 fall together with claim 1.

Hikosaka:

ISSUE

Does the preponderance of evidence on this record support the Examiner's finding that Hikosaka teaches the subject matter of Appellants' claimed invention?

FACTUAL FINDINGS

FF 9. Hikosaka teaches "[a] composition of matter for use in a solid drug product for 4-(cis-p-menthane-8-irioxide) benzanilide (hereinafter AS-56C) . . . whereby AS-56C exists in amorphous form in a solution of one . . . of . . . hydroxypropyl methylcellulose acetate succinate" mixed ester (Hikosaka 1: col. 1, 1. 9 - col. 2, 1. 2; *see also* Ans. 6).

FF 10. Hikosaka teaches that

The composition of matter referred to in this invention is produced as follows. A compound of AS-56C and one . . . of the base chemicals referred to above [(e.g., hydroxypropyl methylcellulose acetate succinate mixed ester)] is dissolved in

an organic solvent, and the solvent is then removed . . . [by], for example spray drying.

(Hikosaka 2: col. 1, ll. 7-15; *see also* Ans. 6.)

ANALYSIS

We find no persuasive evidence or argument on this record to support Appellants' contention that Hikosaka "is non-enabling" (App. Br. 8). *See Impax Labs., Inc. v. Aventis Pharms. Inc.*, 468 F.3d at 1382.

We recognize Appellants' recitation of the limitations of claims 4, 49, 53, and 54 and contention that Hikosaka fails to teach the recited limitations (App. Br. 8). However, as the Examiner points out, these limitations are "the properties of the composition" (Ans. 6). "When the claimed compositions are not novel they are not rendered patentable by recitation of properties, whether or not these properties are shown or suggested in the prior art." *In re Spada*, 911 F.2d 705, 709 (Fed. Cir. 1990).

CONCLUSION OF LAW

The preponderance of evidence on this record supports the Examiner's finding that Hikosaka teaches the subject matter of Appellants' claims 1, 4, 49, 53, and 54. Accordingly, the rejection of claims 1, 4, 49, 53, and 54 under 35 U.S.C. § 102(b) as being anticipated by Hikosaka is affirmed. Since they are not separately argued claims 55 and 56 fall together with claim 1.

Obviousness:

Miyajima or Kigoshi:

Appellants address Miyajima and Kigoshi together (*see* App. Br. 9-10). We do the same.

ISSUE

Does the preponderance of evidence on this record support a conclusion of obviousness?

FACTUAL FINDINGS

FF 11. We incorporate FF 1-8 above by reference.

FF 12. The Examiner finds that, absent evidence to the contrary, since Miyajima's formulation, Kigoshi's formulation, and Appellants' claimed formulation are all spray dried, it would be reasonable to expect that the residual solvent in the formulations would be the same. (Ans. 7).

FF 13. Appellants admit that Miyajima and Kigoshi teach spray drying a composition onto a core that is less than 100 microns in diameter (App. Br. 9-10).

FF 14. The Examiner finds that "when a core of less than 100 microns are [sic] spray coated, then it flows that the spray coated particles must be less than 100 microns" (Ans. 14).

ANALYSIS

For the reasons set forth above, claim 1 is anticipated by both of Miyajima and Kigoshi. "[A]nticipation is the epitome of obviousness." *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983). Accordingly, we are not persuaded by Appellants' contentions regarding claim 1 (App. Br. 9).

Appellants contend that the Examiner failed to establish a prima facie case of obviousness with regard to claims 50 and 51 (*id.*). We are not persuaded (*see* FF 12).

While Appellants admit that both of Miyajima and Kigoshi suggest a particle core that is less than 100 microns in diameter (FF 13), Appellants' contend that the Examiner failed to establish that the spray dried particles of Miyajima and Kigoshi are also less than 100 microns in diameter (App. Br. 9-10). We are not persuaded (*see* FF 14).

CONCLUSION OF LAW

The preponderance of evidence on this record supports a conclusion of obviousness. The rejections of claims 1, 23, 50, and 51 under 35 U.S.C. § 103(a) as unpatentable over both of Miyajima and Kigoshi is affirmed.

The combination of Kigoshi, Madhusoodanan, and Bymaster:

ISSUE

Does the preponderance of evidence on this record support a conclusion of obviousness?

FACTUAL FINDINGS

FF 15. We incorporate FF 4-8 above by reference.

ANALYSIS

As discussed above claims 1, 4, 49, 51, and 54 are anticipated by Kigoshi. “[A]nticipation is the epitome of obviousness.” *Connell v. Sears, Roebuck & Co.*, 722 F.2d at 1548. Accordingly, we are not persuaded by Appellants' contentions regarding claims 1, 4, 49, 51, and 54 (App. Br. 10-12).

CONCLUSION OF LAW

The preponderance of evidence on this record supports a conclusion of obviousness. The rejection of claims 1, 4, 49, 51, and 54 under 35 U.S.C. § 103(a) as unpatentable over the combination of Kigoshi, Madhusoodanan, and Bymaster is affirmed. Because they are not separately argued claims 36, 37, 50, 53, 55, and 56 fall together with claim 1.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

DEA

cdc